

ELECTRONICALLY FILED JANUARY 28, 2009

<b>PETITION FOR CERTIFICATE OF CORRECTION</b>		
Address to:	Attorney Docket	SKEL-007
Mail Stop Certificate of Correction Branch	First Named Inventor	DELANEY, DAVID
Commissioner for Patents	Patent Number	7,306,786
P.O. Box 1450	Issue Date	December 11, 2007
Alexandria, VA 22313-1450	Application Number	10/629,321
	Filing Date	July 28, 2003
	Title:	<i>"CALCIUM PHOSPHATE CEMENTS COMPRISING A WATER-SOLUBLE CONTRAST AGENT"</i>

Sir:

Transmitted herewith for filing is a Certificate of Correction for the above-identified patent to correct typographical errors reflected on the Issued Patent as follows:

In Column 11, line 40, after the word "comprising" insert an additional line and insert the following word:

**combining:**

Enclosed is a copy of the Amendment dated June 8, 2007, which was received at the U.S. Patent Office on June 8, 2007 showing the correct listing of the claims. Also enclosed is a copy of Column 11 of the issued patent correction requested.

It is believed that no fee is due since the error was made by the Patent and Trademark Office. However, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. § 1.20, which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815 order number SKEL-007.

Respectfully submitted,

BOZICEVIC, FIELD & FRANCIS LLP

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## UNITED STATES PATENT AND TRADEMARK OFFICE CERTIFICATE OF CORRECTION

Page 1 of 1

PATENT NO. : 7,306,786

APPLICATION NO.: 10/629,321

ISSUE DATE : December 11, 2007

INVENTOR(S) : DELANEY, DAVID

It is certified that an error appears or errors appear in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 11, line 40, after the word "comprising" insert an additional line and insert the following word:

**combining:**

MAILING ADDRESS OF SENDER (Please do not use customer number below):

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This collection of information is required by 37 CFR 1.322, 1.323, and 1.324. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 1.0 hour to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Attention Certificate of Corrections Branch, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

# VIA EXPRESS MAIL EV 687 639 351 US

<b>AMENDMENT &amp; RESPONSE TO</b>  Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Attorney Docket No.	SKEL-007
	Confirmation No.	6585
	First Named Inventor	DELANEY, DAVID
	Application Number	10/629,321
	Filing Date	July 28, 2003
	Group Art Unit	1618
	Examiner Name	Jones, Dameron Levest
	Title:	"CALCIUM PHOSPHATE CEMENTS COMPRISING A WATER-SOLUBLE CONTRAST AGENT"

Sir:

This communication is responsive to the Office Action dated May 18, 2007 for which a three-month period for response was given making this response due by August 18, 2007.

**AMENDMENTS**

In the claims:

1. (Currently Amended) A method of producing a flowable composition that sets into a calcium phosphate containing mineral product, said method comprising:

combining:

- (a) a setting fluid;
- (b) dry reactants comprising a calcium source and a phosphate source; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate product;

~~in a ratio sufficient to produce said flowable material comprising poorly crystalline calcium phosphate mineral, wherein said poorly crystalline that sets into a calcium phosphate mineral product that includes atoms of said radio-opaque element incorporated into said mineral product.~~

2. (Original) The method according to Claim 1, wherein said setting fluid comprises said water-soluble contrast agent.

3. (Original) The method according to Claim 1, wherein said dry reactants comprise said water-soluble contrast agent.

4. (Original) The method according to Claim 1, wherein said water-soluble contrast agent comprises a salt of a radio-opaque element.

5. (Cancelled)

6. (Original) The method according to Claim 4, wherein said radio-opaque element is one that is incorporated into a calcium phosphate apatite structure of said calcium phosphate containing product.

7. (Original) The method according to Claim 4, wherein said radio-opaque element is chosen from barium, oxalate, zirconium, tantalum and tungsten.

8. (Original) The method according to Claim 7, wherein said radio-opaque element is barium.

9. (Original) The method according to Claim 8, wherein said salt of said radio-opaque element is barium chloride.

10. (Currently Amended) The method according to Claim 1, wherein said ~~ratio of~~ said dry reactant to setting fluid are combined in a ratio that ranges from about 0.2:1 to 0.7:1.

11. (Original) The method according to Claim 10, wherein said flowable composition is a paste.

12. (Original) The method according to claim 1, wherein said setting fluid is a solution of a soluble silicate.

13. (Original) The method according to Claim 1, wherein said flowable composition sets into said calcium phosphate containing product in a period of time ranging from about 5 to 10 minutes.

14. (Original) The method according to Claim 1, wherein said calcium phosphate containing product has a compressive strength ranging from about 25 to 100 MPa.

15. (Currently Amended) A method of producing a paste that sets into a calcium phosphate containing mineral product, said method comprising:

(a) combining:

- (i) dry reactants comprising a calcium source and a phosphate source;
- (ii) a setting fluid; and
- (iii) a water-soluble barium salt;

~~wherein said dry reactants, setting fluid and water-soluble barium salt are combined in a ratio sufficient to provide for said paste; and~~

(b) mixing said combined reactants and setting fluid ~~for a sufficient period of time~~ to produce a paste that sets capable of setting into a calcium phosphate containing mineral product.

16. (Original) The method according to Claim 15, wherein said setting fluid comprises said water-soluble barium salt.

17. (Original) The method according to Claim 15, wherein said dry reactants comprise said water-soluble barium salt.

18. (Original) The method according to Claim 15, wherein said water-soluble barium salt is barium chloride.

19. (Original) The method according to claim 15, wherein said setting fluid is a solution of a soluble silicate.

20. (Original) The method according to Claim 15, wherein both said setting fluid and dry reactants comprise said water-soluble barium salt.

21. (Original) The method according to Claim 15, wherein said flowable composition sets into said calcium phosphate containing product in a period of time ranging from about 5 to 10 minutes.

22. (Original) The method according to Claim 15, wherein said calcium phosphate containing product has a compressive strength ranging from about 25 to 100 MPa.

23. (Original) A flowable composition that sets into a calcium phosphate containing product, wherein said composition is produced by the method according to Claim 1.

24. (Cancelled)

25. (Currently Amended) A kit for use in preparing a flowable composition that sets in an in vivo fluid environment into a calcium phosphate mineral product comprising calcium phosphate molecules, said kit comprising:

- (a) dry reactants comprising a calcium source and a phosphate source;
- (b) a setting fluid or components for producing the same; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate mineral product, ~~comprising poorly crystalline calcium phosphate mineral~~, wherein said ~~poorly crystalline~~ calcium phosphate mineral product includes atoms of said radio-opaque element incorporated into said mineral product.

26. (Currently Amended) A packaged calcium phosphate cement, said packaged cement comprising:

a tubular element separated into a first compartment and at least one additional compartment by a removable barrier;

- (i) dry reactants comprising a source of calcium and phosphate present in said first compartment;
- (ii) a setting fluid or components thereof present in said at least one additional compartment; and

(iii) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into a calcium phosphate mineral product ~~comprising poorly crystalline calcium phosphate mineral~~, wherein said ~~poorly crystalline~~ calcium phosphate mineral product includes atoms of said radio-opaque element incorporated into said mineral product, wherein said calcium phosphate mineral product is produced upon combination of said dry reactants and setting fluid, wherein said water-soluble contrast agent is present in either said first compartment, said at least one additional compartment or in a second additional compartment.

27. (Original) The packaged calcium phosphate cement according to Claim 26, wherein said removable barrier is a clip.

28. (Original) The packaged calcium phosphate cement according to Claim 26, wherein said removable barrier is a frangible barrier.

29. (Original) The method according to claim 26, wherein said setting fluid is a solution of a soluble silicate.

30. (Previously Presented) The method according to Claim 1, wherein said contrast agent is present in an amount ranging from about 10 to about 35% by weight.

**REMARKS**

In view of the following remarks, the Examiner is requested to allow Claims 1-4, 6-23 and 25-30, the only claims pending and under examination in this application.

The Examiner is thanked for the personal interview held with the undersigned on June 7, 2007. During the interview, the above amendments were discussed and agreement was reached that the above amendments would address the issues raised by the Examiner in the May 18, 2007 office action.

The claims have been amended solely to clarify the claim language. No new matter has been added. As no new matter has been added by way of these amendments, their entry is respectfully requested.

Claims 1-23 and 25-30 have been rejected under 35 U.S.C. § 112, second paragraph for a number of asserted reasons. In view of the above amendments, it is believed that this rejection may be withdrawn.

**CONCLUSION**

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number SKEL-007.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP

Date: June 8, 2007

By: 

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Tricalcium phosphate 6.20 g). The three different cement formulations were as follows:

1. Cement formula 1 contained 35% barium by weight. The Calcium plus Barium to phosphate molar ratio was 1.67. (Ca+Ba/PO<sub>4</sub>)
2. Cement formula 2 contained 22% barium by weight. The Calcium plus Barium to phosphate molar ratio was 1.50. (Ca+Ba/PO<sub>4</sub>)
3. Cement formula 3 contained 12% barium by weight. The Calcium plus Barium to phosphate molar ratio was 1.40. (Ca+Ba/PO<sub>4</sub>)

2% sodium silicate solution was added to each of the above cement formulations to make a paste and plastic washers were filled with the resultant past to make specimens for clinical x-ray. Increasing radioopacity was observed with increasing barium content.

It is evident from the above results and discussion that calcium phosphate cements that are readily viewable under X-ray imaging technologies are provided. Benefits of the subject cements include extremely low toxicity, as the contrast element employed in the subject methods is rapidly incorporated into the calcium phosphate product of the subject cements, thereby minimizing systemic exposure of the host to the contrast agent. As such, the subject invention represents a significant contribution to the art.

All publications and patent applications mentioned in this specification are herein incorporated by reference to the same extent as if each individual publication or patent application was specifically and individually indicated to be incorporated by reference.

The invention now being fully described, it will be apparent to one of skill in the art that many changes and modifications can be made thereto without departing from the spirit and scope of the appended claims.

What is claimed is:

1. A method of producing a flowable composition that sets into a calcium phosphate mineral product, said method comprising:

- (a) a setting fluid;
- (b) dry reactants comprising a calcium source and a phosphate source; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate product wherein said water-soluble contrast agent comprises a salt of a radio-opaque element;

to produce said flowable material that sets into a calcium phosphate mineral product that includes atoms of said radio-opaque element incorporated into said mineral product.

2. The method according to claim 1, wherein said setting fluid comprises said water-soluble contrast agent.

3. The method according to claim 1, wherein said dry reactants comprise said water-soluble contrast agent.

4. The method according to claim 1 wherein said radio-opaque element is one that is incorporated into a calcium phosphate apatite structure of said calcium phosphate containing product.

5. The method according to claim 1 wherein said radio-opaque element is chosen from barium, oxalate, zirconium, tantalum and tungsten.

6. The method according to claim 5, wherein said radio-opaque element is barium.

7. The method according to claim 6, wherein said salt of said radio-opaque element is barium chloride.

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8. The method according to claim 1, wherein said dry reactant to setting fluid are combined in a ratio that ranges from about 0.2:1 to 0.7:1.

9. The method according to claim 8, wherein said flowable composition is a paste.

10. The method according to claim 1, wherein said setting fluid is a solution of a soluble silicate.

11. The method according to claim 1, wherein said flowable composition sets into said calcium phosphate containing product in a period of time ranging from about 5 to 10 minutes.

12. The method according to claim 1, wherein said calcium phosphate containing product has a compressive strength ranging from about 25 to 100 MPa.

13. A method of producing a paste that sets into a calcium phosphate mineral product, said method comprising:

- (a) combining:
  - (i) dry reactants comprising a calcium source and a phosphate source
  - (ii) a setting fluid; and
  - (iii) a water-soluble barium salt; and
- (b) mixing said combined reactants and setting fluid to produce a paste that sets into a calcium phosphate mineral product.

14. The method according to claim 13, wherein said setting fluid comprises said water-soluble barium salt.

15. The method according to claim 13, wherein said dry reactants comprise said water-soluble barium salt.

16. The method according to claim 13, wherein said water-soluble barium salt is barium chloride.

17. The method according to claim 13, wherein said setting fluid is a solution of a soluble silicate.

18. The method according to claim 13, wherein both said setting fluid and dry reactants comprise said water-soluble barium salt.

19. The method according to claim 13, wherein said flowable composition sets into said calcium phosphate containing product in a period of time ranging from about 5 to 10 minutes.

20. The method according to claim 13, wherein said calcium phosphate containing product has a compressive strength ranging from about 25 to 100 MPa.

21. A flowable composition that sets into a calcium phosphate containing product, wherein said composition is produced by the method according to claim 1.

22. A kit for use in preparing a flowable composition that sets in an in vivo fluid environment into a calcium phosphate mineral product comprising calcium phosphate molecules, said kit comprising:

- (a) dry reactants comprising a calcium source and a phosphate source;
- (b) a setting fluid or components for producing the same; and
- (c) a water-soluble contrast agent comprising a radio-opaque element other than calcium that is incorporated into said calcium phosphate mineral product, wherein said calcium phosphate mineral product includes atoms of said radio-opaque element incorporated into said mineral product.

23. A packaged calcium phosphate cement, said packaged cement comprising:

a tubular element separated into a first compartment and at least one additional compartment by a removable barrier;

- (i) dry reactants comprising a source of calcium and phosphate present in said first compartment;